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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/773,351	MAES ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/3/2006
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment submitted January 13, 2006. Claims 1 and 3-20 are pending in the application, and are being examined on the merits herein.

The Examiner acknowledges Applicant's indication that, if a necessary, a terminal disclaimer will be filed to obviate the provisional obviousness-type double patenting rejection over co-pending Application No. 10/424,616, in the event that allowable subject matter is indicated. However, as no terminal disclaimer has as-yet been filed, the provisional obviousness-type double patenting rejection is being maintained.

Applicant's arguments regarding the rejections of the claims over the prior art have been fully considered but they are not persuasive. The rejections of record are being maintained.

The claims are rejected as follows.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribier et al. (5,650,166) for the same reasons of record as in the previous action dated August 18, 2005.

Ribier et al. discloses a moisturizing composition for the treatment of surface and deep layers of the skin clear comprising the instant ingredients such as cholesterol sulfate in the salt of alkali metal (including potassium) (see col. 3, lines 64-67), N-acetyglucosamine (see col. 5, lines 59-67), the particular sterol, cholesterol (see col. 3 line 60 and col. 6, lines 47-49), fatty acids, including linoleic acid (see col. 6, lines 44-46.) Ribier et al. further teaches the use of plant extracts (see col. 7, lines 5-8.) The compositions of Ribier et al. may be an emulsion, gel, lotion, and ointment form (see col. 7, lines 10-14.)

Thus the disclosure of Ribier et al. anticipates claims 1 and 3-9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-4, 6-9, 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (5,925,364, of record) in view of Sebag et al. (5,411,742, of record) for the same reasons of record as stated in the previous Office Action mailed on August 18, 2005.

Ribier et al. discloses a cosmetic or dermatological composition comprising the ionic amphiphilic lipids such as the alkali metal salts of cholesterol sulphate, in particular the sodium salt, in an amount of 2-6% by weight, and preferably 3-4% by weight (see col. ,lines 43-48 and 54-55, col. 4, lines 12-15), salicylic acid (a known exfoliant) (see claim 18 at col. 15 line 6), keratolytic agents (known exfoliants) (see col. 5 line 36, claim 15 at col. 14, lines 49), fatty acids broadly (see col. 4 line 60, claim 18 at col. 15 line 5), and Centella asiatica extract (see col. 4 line 64, claim 1 at col. 15 line 8.) The cosmetic or dermatological composition of Ribier et al. is known to be topically applicable to skin.

Ribier et al. does not expressly disclose the employment of the particular fatty aid, linoleic acid, and cholesterol in the composition herein. The prior art also does not expressly disclose the amount of an exfoliant in the composition herein.

Sebag et al. discloses a cosmetic or dermatological composition comprising the salts of cholesterol (see col. 2 line 3), salicylic acid or its derivatives (known exfoliants) in amount of 3-10% by weight (see abstract, col. 3 lines 26-36), keratolytic agents (known exfoliants) (see col. 6 line 66), the particular fatty acid , linoleic acid (see claim 10 at col. 17 line 17), and cholesterol (see claim 8 at col. 17 lines 5-6.)

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular fatty acid, linoleic acid, and cholesterol in the composition of Ribier et al and to optimize the effective amounts of exfoliant in the composition herein to about 10% by weight.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular fatty acid, linoleic acid, and cholesterol in the composition of Ribier et al, since fatty acids broadly and the particular fatty acid, linoleic acid, and known to be useful in a cosmetic or dermatological composition for treating skin based on the prior art. Moreover, cholesterol is well known to be used as a cosmetic or dermatological composition for treating skin according to Sebag. Therefore, one of ordinary skill in the art would have reasonably expected that combining the

composition of Ribier et al and the composition of Sebag known to be useful for the same purpose, treating skin, in a composition to be administered would improve the therapeutic effect for treating skin.

Since all active composition components herein are known to be used to treat skin it is considered prima facie obvious to combine then into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonable expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980.)

Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of the alkali metal salts of cholesterol sulphate and an exfoliant in the composition because their amounts are known in the art and the optimization of known amounts of active agents to be administered is consider well within the skill of the artisan. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPW 215 (CCPA 1980.)

Thus, the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Claims 13-20 are rejected under 35 U.S.C. 103(a) as begin unpatentable over Ribier et al. (5,650,166) for the same reasons of record in the previous Office Action mailed August 18, 2005.

The same disclosure of Ribier et al. (5,650,166) has been discussed in the 102(b) rejection set forth above.

The cited prior art does not expressly disclose the amount of each instant ingredient.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the amount of the known particular agents taught in Ribier et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the amount of the known particular agents taught in Ribier et al. since the determination or optimization of amounts of known cosmetic agents, is considered well within conventional skills in pharmaceutical science, involving merely routine skill in the art.

It has been held that is it within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USQ 215 (CCPA 1980.)

Claims 10-12 and 20 are rejected under 35 U.S.C. 103(a) as begin unpatentable over Ribier et al. (5,650,166) and further in view of Subbiah (6,150,381) and Ichinose et al. (5,702,691) for the reasons of record stated in the Office Action mailed on August 18, 2005.

The claims are directed to compositions further comprising sclareolide and white birch extract.

The same disclosure of Ribier et al. (5,650,166) has been discussed in the 102(b) rejection set forth above.

The cited prior art does nor expressly disclose the employment of sclareolide and white birch extract.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add or employ sclareolide and white birch extract in the composition of Ribier et al.

Subbiah teaches the use of sclareolide in topical formulations, particularly for acne (see abstract.) Sclareolide is taught in combination with other ingredients (see col. 5, line 6 through col. 7, line 12.) Subbiah teaches that sclareolide has antimicrobial activity that is useful in the treatment of acne (see col. 4, lines 45-65.)

Ichinose teaches that white birch extracts are known anti-inflammatory agents (see col. 5, lines 4-13.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Ribier et al. by the addition of sclareolide for its anti-acne properties as taught by Subbiah and by the addition of white birch extract for its anti-inflammatory properties as taught by Ichinose. The motivation for modification comes from the benefit of such properties in formulating cosmetic compositions. The missing ingredients have art-recognized suitability for the intended purpose of formulation cosmetic compositions. The selection of a known material based on its suitability for its intended use has been determined to be prima facie obvious. See Sinclair and Carroll Co. F. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945), In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPS 1960); and MPEP 2144.07.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/424,616 for the reasons of record stated in the Office Action mailed August 18, 2006.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the copending application and the instant application are

drawn to a skin/cosmetic composition containing cholesterol sulfate, fatty acids, and a sterol (such as cholesterol) and methods employing the compositions. Thus, the copending Application No. 10/424,616 and the instant claims are seen to substantially overlap.

Thus, the instant claims are seen to be obvious over all the claims of copending Application No. 10/424,616.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed January 13, 2006 have been fully considered but they are not persuasive.

In particular, Applicant's argue that the cited references do not teach a composition comprising an "integral mixture" of cholesterol sulfate with the exfoliant, as recited in the claims. Applicants argue that the cited references (Ribier et al. references) teach the formation of a composition having discrete layers or vesicles, and thus do not teach an "integral mixture."

The Examiner respectfully notes that the claims are given their broadest possible reasonable interpretation during examination. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The broadest reasonable interpretation of the composition having an "integral mixture" of the cholesterol sulfate with the exfoliant is that the composition comprises a mixture of the cholesterol sulfate that is formed as a unit with another part of the mixture, which is consistent with the dictionary definition of integral as disclosed in the Merriam-Webster Online Dictionary (formed as a unit with another part <a seat with integral headrest.) The prior art teaches and/or suggests such a composition, because the prior art teaches or suggests combining the cholesterol sulfate with the exfoliant in a single cosmetic composition (an single unit), and thus the components form an integral mixture in the composition because each part forms a unit (the composition) with another part.

Applicants argue that an integral mixture is not a lipid vesicle, and thus that the Ribier et al. references do not teach or suggest the claimed invention. Applicants argue that the vesicles in these references are not integrally mixed, but rather are used to form separate and discrete entities present in the aqueous phase. However, the Examiner respectfully notes that the claims recite an "integral mixture," which given its broadest possible reasonable interpretation means a mixture that has components that form a unit (i.e. a composition) with one another, which is taught by the Ribier et al. references,

and includes even compositions having distinct phases and vesicles, as these phases and vesicles nonetheless make up parts of a single unit (the composition.)

The Examiner furthermore notes that, in rebutting a prior new matter rejection of the phrase "integral with" under 35 U.S.C. 112, Applicants argued in the response submitted June 23, 2004 that:

> "The Examiner admits that "[t]he recitation 'integral with' could be interpreted as 'mixed with' or 'a mixture of' according [sic] its plain and ordinary meaning. Applicants fully agree with this interpretation ..." (page 2 of Amendment Arguments Submitted June 23, 2004.)

Thus, Applicants appear to have already accepted the plain meaning of "integral with" as being "mixed with" or "a mixture of," according to their own admission. An "integral mixture" as instantly claimed thus clearly encompasses a mixture having the components combined together that makes up a single unit, such as a single composition, as is taught and/or suggested by the references cited above.

It is furthermore noted that the instant Specification does not provide support under 35 U.S.C. 112, first paragraph, for a definition of "integral mixture" that excludes compositions having vesicles or two or more phases. Instead, the specification teaches that the composition provides "integrated results" because the two components

(exfoliant and cholesterol sulfate) do not cancel out each other's effects (see page 4, lines 21-29.) Thus, the specification specifically refers to "integrated" in the sense that effects provided by each component are not canceled out by one another. The specification does not disclose that such compositions are required to be absent vesicles or multiple phases, and does not otherwise explicitly define "integral" or "integral mixture" to mean anything other than its ordinary plain meaning.

Applicants furthermore provide a declaration signed by Philip Wesley Wertz, which was originally provided in Application No. 08/865,821, to show that providing cholesterol sulfate in a composition is not obvious or inherent over a teaching of providing a cholesterol in general, in a composition. The Examiner notes that the Ribier et al. references teach providing cholesterol sulfates in topical compositions, and thus provide sufficient motivation for the preparation of a composition comprising such a compound.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC

SREENI PADMANABHAN
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